

IRB Issues and Potential Solutions
Research Subcommittee of the Faculty Senate
Based on the Meeting of Feb. 8, 2005

Background

1. Dr. Steven Kaminsky and Dr. Richard Levine of the Research Office met with the Research Subcommittee of the Faculty Senate on Feb. 8, 2005 to discuss the IRB at USUHS.
2. The Research Subcommittee has received comments from faculty expressing concern about the way the IRB process has worked in the past. The discussion at this meeting summarized these concerns, summarized recent changes in the IRB office that have begun to address the concerns, and considered other solutions that could potentially improve the IRB process further.
3. On behalf of the USUHS Faculty, the Research Subcommittee thanks Dr. Kaminsky and Dr. Levine for the time invested in a fruitful dialogue and their commitment to improving the IRB process at the University.

Recent changes in the IRB office

1. The Research Subcommittee appreciates Rick Levine's exceptionally helpful contributions to the IRB process, including the changes he has implemented during his recent but temporary return to direct. There is concern, however, about what will happen when he no longer fills that role and about the extent to which the quality of the IRB process depends on one individual.
2. The Research Subcommittee recognizes the hard work and long hours that the staff in the IRB office invest to maintain the functionality of the IRB. The fact that they frequently work overtime suggests that they are understaffed and/or lack adequate electronic or other support for efficient work.
3. One recent change that is especially helpful to researchers in collaborative research projects is an IRB authorization agreement.
4. A change currently in process is the development of a template for protocols submitted to the IRB for review. This template will clarify all required components of a complete protocol and specify required language for informed consent documents and sections of the protocol that describe protections for human research participants.

Areas for Further Improvement

1. Lost or misplaced protocols cause significant delays in the IRB process, complicating the review process for both IRB staff and the faculty. This can potentially result in loss or delay of funding.
2. A more efficient submission and review process will result in more effective use of researchers' time and a more effective research effort at the University.

Recommendations

1. Replace or substantially update the current 3204 form in conjunction with the development of a template for protocols.
2. Create a streamlined process for student protocols.

3. Increase the support staff in the IRB office.
4. Develop an electronic tracking system to assist IRB Staff and the Faculty in following protocols through the IRB review process.
5. Improve communication between the representatives of the Faculty.
 - a. Establish a process by which REA/IRB informs the Faculty about IRB issues that are under revision. This could be regular email from REA/IRB to the chair of the Research Subcommittee, who would then circulate information to the Subcommittee and the Faculty.
 - b. Specifically request the Faculty's input through the Research Subcommittee. Possible mechanisms include
 - i. Circulate draft documents (e.g., the template for protocols submitted to the IRB) to the Research Subcommittee for comment.
 - ii. Invite representatives from the Research Subcommittee to attend a working session on a particular issue.
 - iii. Return to future Research Subcommittee meetings on a regularly-scheduled basis (2-4 times/year) for a working session on specified issues.
 - iv. Invite representatives from the Research Subcommittee to participate in a research advisory group.
 - v. Engage members of a proposed research advisory group in the activity of the Research Subcommittee.
 - c. Provide regular updates about the IRB and other research issues to the Faculty Assembly and/or on the USUHS website with periodic email messages to the faculty.